

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

)
IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS

) Judge Patti B. Saris
THIS DOCUMENT RELATES TO:)

The City of New York v. Abbott Labs., et al.)
(S.D.N.Y. No. 04-CV-06054))
County of Suffolk v. Abbott Labs., et al.)
(E.D.N.Y. No. CV-03-229))
County of Westchester v. Abbott Labs., et al.)
(S.D.N.Y. No. 03-CV-6178))
County of Rockland v. Abbott Labs., et al.)
(S.D.N.Y. No. 03-CV-7055))
County of Dutchess v. Abbott Labs, et al.)
(S.D.N.Y. No. 05-CV-06458))
County of Putnam v. Abbott Labs, et al.)
(S.D.N.Y. No. 05-CV-04740))
County of Washington v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00408))
County of Rensselaer v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00422))
County of Albany v. Abbott Labs, et al)
(N.D.N.Y. No. 05-CV-00425))
County of Warren v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00867))
Essex County v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00456))
County of Onondaga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00088))

County of Tompkins v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00397))
County of Cayuga v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00423))
County of Madison v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00714))
County of Cortland v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00881))
County of Herkimer v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00415))
County of Oneida v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00489))
County of Fulton v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00519))
County of St. Lawrence v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00479))
County of Jefferson v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00715))
County of Lewis v. Abbott Labs, et al.)
(N.D.N.Y. No. 05-CV-00839))
County of Chautauqua v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06204))
County of Allegany v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06231))
County of Cattaraugus v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06242))
County of Genesee v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06206))
County of Wayne v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06138))
County of Monroe v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06148))
County of Yates v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06172))
County of Niagara v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06296))
County of Seneca v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06370))
County of Orleans v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06371))
County of Ontario v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06373))
County of Schuyler v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06387))

County of Steuben v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06223))
County of Chemung v. Abbott Labs, et al.)
(W.D.N.Y. No. 05-CV-06744))
AND)
County of Nassau v. Abbott Labs, et al.)
(E.D.N.Y. No. 04-CV-5126))

)

**DEFENDANTS¹ JOINT MEMORANDUM OF LAW IN SUPPORT OF MOTION
TO DISMISS (1) THE CONSOLIDATED COMPLAINT OF NEW YORK CITY
AND PLAINTIFF NEW YORK COUNTIES OTHER THAN NASSAU AND (2) THE
SECOND AMENDED COMPLAINT OF NASSAU COUNTY**

¹ Each defendant has joined in this Motion only as to those cases in which the defendant is a party. In addition, defendants included herein reserve all rights to subsequently move to dismiss the Consolidated Complaint and the Nassau County Second Amended Complaint on the basis of improper jurisdiction.

Preliminary Statement²

New York City and forty New York counties, represented by one law firm, have joined as plaintiffs in a “Consolidated Complaint” (“Cons. Comp.”) that, but for a voluntarily dropped RICO count, reiterates the same causes of action that this Court dismissed under Fed. R. Civ. P. 12(b)(6) in its previous decisions involving Suffolk County (*County of Suffolk v. Abbott Labs, et al.*, 339 F. Supp. 2d 165 (D. Mass. Sep. 30, 2004) (*Suffolk I*); *County of Suffolk v. Abbott Labs, et al.*, 2004 WL 2387125 (D. Mass. Oct. 26, 2004) (*Suffolk II*); November 23, 2004 *Clarification Order*, April 8, 2005 *Memorandum and Order* (*Suffolk III*); and *The Commonwealth of Massachusetts v. Mylan Labs*, 357 F. Supp. 2d 314 (D. Mass. 2005)).³ Plaintiff Nassau County, represented by another firm, sues separately in a Second Amended Complaint (“Nassau SAC”) that largely follows the Consolidated Complaint and also seeks to revive the previously-dismissed RICO count. The claims in both pleadings—(i) RICO (based on a publisher-manufacturer “enterprise”); (ii) implied private right of action under the federal Medicaid rebate statute; (iii) breach of contract (as alleged third-party beneficiaries of rebate agreements); and (iv) common law fraud – should be dismissed for the same reasons this Court previously gave. Nothing in either the Consolidated Complaint or the Nassau SAC even remotely provides a basis for

² References to individual case names in which New York City or a New York county is a plaintiff are in italics, e.g. *Suffolk*. References to the plaintiff city or county itself in those Cases are by name of the city or county without italics, e.g. Suffolk.

³ Suffolk County has not joined in the Consolidated Complaint *except* as to certain defendants whom it did not name in its own complaint. Nor has Suffolk County moved to be permitted to reassert against the original defendants its claims that were dismissed by this Court. Thus, this Court’s rulings still apply to Suffolk itself. Evidently, however, New York City and the other counties in the Consolidated Complaint and Nassau do not believe that they are affected by the prior decisions of this Court in the Suffolk matter. Defendants’ position is that the parties and the Court have expressly stipulated and proceeded on the basis that *Suffolk* is the “lead” county case and that the Court’s rulings in *Suffolk* do apply to the other county cases under law of the case and/or stare decisis. The new complaints are, in effect, out-of-time motions for the Court to reconsider its rulings in *Suffolk*.

reconsideration (for that is what plaintiffs effectively request) of this Court’s prior decisions. *See Point I infra.*

Other causes of action as to which this Court initially reserved decision in *Suffolk* should also now be dismissed under Fed. R. Civ. P. 12(b)(6). *See Point II infra.* This Court had earlier wanted the benefit of New York’s highest court’s interpretation of N.Y. General Business Law § 349 on the question of whether the Counties, as “indirect purchasers” under the State’s Medicaid program, can state a cause of action under that statute. Now that the New York Court of Appeals has ruled, it is clear that these plaintiffs do *not* have a claim under that statute. This Court also deferred resolution of whether the Counties possess implied private rights of action under New York state health legislation and regulations. *Suffolk I*, 339 F. Supp. 2d at 182-83. Implying such rights would run counter to the New York Legislature’s intent, as recent public testimony on the Counties’ role in Medicaid shows.

In Point III, defendants turn to Suffolk’s one statutory cause of action that this Court previously deemed “colorable” under Rule 12(b)(6) – but only as to an alleged “AWP Fraud” not as to a “Best Price” claim – the count under New York Social Service Law Section 145-b. Defendants respectfully submit that this Court misconstrued the statute. It is a *sine qua non* for application of the statute that a defendant have *obtained* public funds, not merely that the defendant be alleged to have made statements in aid of another (*e.g.* Medicaid pharmacists) who obtained such funds. Accordingly, no Section 145-b action may lie against these defendants.

Finally, the Consolidated Complaint and the Nassau SAC fail to meet the standards of Fed. R. Civ. P. 8(a) and 9(b). *See Point IV infra.* This Court has already ruled that virtually all of Suffolk’s “Best Price” claims – including the one common law cause of action (unjust enrichment) that had earlier survived the 12(b)(6) analysis – failed because “the allegations fall

woefully short under [those Rules.].” *Suffolk II*, 2004 WL 2387125 at *2. The new pleadings fare no better in asserting claims based on “Best Price” and rebates.

On the other key allegation of “AWP Fraud”, the new pleadings take a step backward. As in the case before this Court involving Massachusetts, plaintiffs now state that “this case is not about the 20-25% mark up between WAC and AWP. . . . This case concerns that . . . WAC itself is false and misleading” Cons. Comp. ¶¶ 7-8. This Court permitted a similar allegation involving WAC to go forward in the Massachusetts case only where plaintiff eventually attached specific calculations on a per-drug, per-manufacturer basis (against thirteen primarily generic defendants). Here, there is no particularized allegation that WAC or its equivalents are “false” as to any of the drugs in these complaints. Finally, to the extent the Complaints seek recovery for physician-administered drugs, they cannot rely on AWP, because New York Medicaid reimburses physician-administered drugs based on acquisition cost, not AWP.

Factual and Procedural Background

This Court is familiar with the factual background concerning New York’s Medicaid program from its past decisions in the *Suffolk* matter. Accordingly, defendants incorporate by reference their prior briefs on those facts and will not repeat them here. Instead, we concentrate (a) on the procedural history of the various “county” and New York City cases and (b) plaintiffs’ futile attempt to plead around the *Suffolk* decisions in the Consolidated Complaint and the Nassau SAC.

The Suffolk, Westchester and Nassau Complaints and Stipulations

Suffolk filed its original Complaint on January 14, 2003, and subsequently filed an Amended Complaint on July 31, 2003. Westchester County was the second county to bring suit. It filed its original Complaint on August 29, 2003. Both counties are represented by the same law

firm, Kirby McInerney & Squire, LLP (the “Kirby Firm”) – which now represents forty-two counties and New York City.

Because Suffolk’s First Amended Complaint and Westchester’s original Complaint were substantially identical, the parties entered into a stipulation on November 14, 2003 (the “*Westchester Stipulation*”) to promote “judicial economy” by making defendants’ response to the *Westchester* complaint dependent on the outcome of this Court’s rulings on defendants’ motion to dismiss the amended Complaint in *Suffolk*.

The *Westchester Stipulation* states in relevant part as follows:

- (1) because “the Westchester Complaint contains similar allegations and claims against certain of the same defendants as the Amended Complaint filed by the County of Suffolk in MDL 1456 (‘Suffolk Amended Complaint’); and
- (2) because “judicial economy would be best served if the motions to dismiss the Suffolk Amended Complaint are decided by Judge Saris before defendants in this action respond to the Westchester Complaint;”
- (3) therefore “as to all defendants who have been served with process or have waived service of process, the time to answer or otherwise respond to the Westchester Complaint shall be extended until the later of (a) 30 days after the posting on Verilaw of Judge Saris’s decision on the Suffolk defendants’ motions to dismiss the Suffolk Amended Complaint, or (b) the time otherwise permitted pursuant to the Federal Rules of Civil Procedure.”

Westchester Stipulation filed November 14, 2003 at 2-3.

On September 10, 2003 and August 4, 2004, Rockland County and New York City, respectively, filed Complaints substantially similar to Suffolk’s First Amended Complaint and to Westchester’s Complaint. Both Rockland and New York City entered into stipulations substantially similar to the *Westchester Stipulation*. See *New York City Stipulation* filed September 13, 2004.

Nassau County, represented by the Milberg, Weiss firm, filed its Complaint on November 24, 2004 in the Eastern District of New York. Defendants filed a Notice of Related

Action with the Judicial Panel on Multidistrict Litigation on December 10, 2004. The Judicial Panel issued a conditional transfer order on January 4, 2004. After the case was transferred to this Court, Nassau filed an Amended Complaint on March 17, 2005, which Amended Complaint was in many respects identical to the Complaints filed on behalf of the Kirby Firm's clients. The parties agreed to put off defendants' time to respond to the Nassau First Amended Complaint pending a decision on the motions to dismiss in *Suffolk*.

The Court's Rulings in Suffolk

In its September 30, 2004 Order (*Suffolk I*), the Court granted in part defendants' motion to dismiss the Amended Complaint in *Suffolk*. The Court dismissed Count I (a RICO claim) for failure to plead a cognizable RICO "enterprise." *Suffolk I*, 339 F. Supp. 2d at 175 (citing the Court's prior decision in *In Re Pharma. Indus. Average Wholesale Price Litig.*, 307 F. Supp. 2d 196, 203-05 (D. Mass. Feb. 24, 2004)). The Court dismissed Count II (violation of Federal Medicaid Statute, 42 U.S.C. § 1396r-8), on the ground that there is no implied cause of action under the federal Medicaid rebate statute. *Id.* at 176-77. The Court then dismissed Count VI (breach of contract), on the ground that Suffolk is not an intended third party beneficiary of the rebate agreements between the manufacturers and the Secretary of Health and Human Services. *Id.* at 177-79. The Court also dismissed Count VIII (Fraud), on the ground that Suffolk could not bring a common law fraud claim because it was a third party to the alleged misrepresentations. *Id.* at 180-81. Finally, the Court dismissed Count V (violation of New York Social Services Law § 145-b) with respect to the Medicaid "best price" allegations, but found that Suffolk had asserted a colorable claim with regard to the alleged AWP fraud. *Id.* at 179-80. The Court stated that it would "revisit the issue" of Suffolk's standing to bring a consumer fraud claim under N.Y. Gen. Bus. Law § 349 after the New York Court of Appeals decided whether a third party has indirect

standing under Section 349. *Id.* at 181-83. The Court also deferred ruling on whether Suffolk had stated claims for implied private rights of action under other state statutes and regulations. *Id.* Finally, the Court stated that it would “address the individual, company-specific motions to dismiss in separate orders.” *Id.* at 183.

In its October 26, 2004 Order (*Suffolk II*), the Court reaffirmed that “all federal claims have been dismissed” in *Suffolk* under Fed. R. Civ. P. 12(b)(6), and then proceeded to address the few remaining state law claims as to individual defendants. *Suffolk II*, 2004 WL 2387125 at *1. The Court dismissed all state law claims that related to the allegedly fraudulent best prices of drugs not specifically itemized in Suffolk’s Amended Complaint because “the allegations fall woefully short under Rules 8(a) and 9(b).” *Id.* at *2. The Court held that “[t]here are insufficient facts alleged to state a claim showing entitlement to relief under any state causes of action.” *Id.* at *3.⁴ Finally, as to certain defendants, the Court dismissed not only the best price claims, but also the AWP claims on the ground that the Amended Complaint failed to state particular facts as to each of them.⁵

⁴ The Court first dismissed best price claims against defendants Agouron Pharmaceuticals, Inc., the Amgen Defendants (Amgen, Inc. and Immunex Corporation), the AstraZeneca Defendants (AstraZeneca Pharmaceuticals L.P. and AstraZeneca US), Aventis Behring L.L.C., Barr Laboratories, Inc., Berlex Laboratories, Inc., Biogen, Inc., Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Company, the Forest Defendants (Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc., Fujisawa Pharmaceutical Company, Ltd., Genentech, Inc., Janssen Pharmaceutica, the Johnson & Johnson Defendants (Johnson & Johnson, Janssen Pharmaceutica LP, Ortho Biotech Products LP, Ortho McNeil Pharmaceuticals, Inc.), MedImmune, Inc., Merck & Co., Inc., Reliant Pharmaceuticals, Warrick Pharmaceuticals, and Wyeth Pharmaceuticals. In a subsequent Clarification Order dated November 23, 2004 the Court extended the ruling to the remaining best price defendants: Bayer Corporation, the GSK Defendants (GlaxoSmithKline P.L.C., SmithKline Beecham Corporation and Glaxo Wellcome, Inc.), Abbott Laboratories, Inc., Pfizer, Inc., TAP Pharmaceutical Products, Inc., and Schering-Plough.

⁵ The Court dismissed these claims against defendants Novartis, Purdue, and Ivax “because there are no factual allegations regarding a spread, internal documents or government investigations from which an inference of fraud can reasonably be made.” *Id.* at *2. The Court further dismissed all claims against Aventis Pharmaceuticals Inc. because Suffolk failed to plead a drug sold by it. *Id.* at *3. In addition, the Court held that Suffolk’s best price claims against Bayer relating to Cipro purchases from Third Quarter 1995 through Third Quarter 2000 were barred by settlement agreements. *Id.* Finally, the Court dismissed all “claims against Sanofi and Pharmacia without prejudice to refiling to clarify the corporate structure and which Defendant is responsible for which drugs.” *Id.*

As to the “Suffolk 13” companies and six other defendants as to whom Suffolk had not alleged specific facts beyond a spread,⁶ the Court deferred ruling on their motions to dismiss until Suffolk disclosed “all documents upon which it relied in calculating the spreads, and provide[d], in writing, a more definite statement of its method of calculation pursuant to Federal Rule of Civil Procedure 12(e).” *Id.* at *2. Suffolk attempted to comply through an affidavit of counsel, which described a process (allegedly employed for all defendants) in which counsel assumed on the basis of his own research that “true” wholesale prices could be ascertained merely by surveying retail prices and dividing by a factor of 1.27. In a Memorandum and Order dated April 8, 2005 (*Suffolk III*), the Court held that counsel’s methodology was “not sufficient to plead allegations of fraud with particularity,” and dismissed all the remaining counts against the “Suffolk 13” defendants plus Amgen, Inc., Chiron Corporation, Fujisawa Pharmaceutical Company, Ltd., Johnson & Johnson, Warrick Pharmaceuticals, and Wyeth.

The Consolidated Complaint and The Nassau SAC

On June 15, 2005, the Kirby firm filed a “Consolidated Complaint” on behalf of New York City and all of its county clients other than Suffolk. Much of that Complaint is materially no different from what the Court analyzed and the parties briefed in *Suffolk I, II* and *III*.⁷ Indeed, some of the “new” language in the Consolidated Complaint (*i.e.*, compared to the Suffolk Amended Complaint) is based on arguments that Suffolk County made, and this Court rejected, in Suffolk’s motion-to-dismiss briefing. For example, allegations that the federal

⁶ The “Suffolk 13” are Agouron Pharmaceuticals, Inc., Barr Laboratories, Inc., Berlex Laboratories, Inc., Biogen, Inc., Eli Lilly and Co., Forest Pharmaceuticals, Inc., Genentech, Inc., Ivax Corporation/Ivax Pharmaceuticals, Inc., Medimmune, Inc., Merck & Col, Inc., Purdue Pharma, L.P., Reliant Pharmaceuticals, and Sanofi-Synthelab, Inc. The other six defendants are Amgen, Inc., Chiron Corporation, Fujisawa Pharmaceutical Company, Ltd., Johnson & Johnson, Warrick Pharmaceuticals and Wyeth.

⁷ A “corrected” copy of the Consolidated Complaint that remedied minor technical errors was filed on June 22, 2005. References herein to the Cons. Comp. are to the “corrected” version.

government impliedly intended New York counties to be beneficiaries of rebate agreements because it knew of and approved of the State's overall Medicaid plan, which disclosed the involvement of counties in the program (Cons. Comp. ¶¶ 103, 121, 877-883), were already made in Suffolk's losing argument in its sur-reply brief. (*See* Suffolk Surreply at p. 1 ("the federal government reviewed and expressly approved New York's Medicaid Plan")).

Otherwise, the primary changes in the Consolidated Complaint are: (1) the emphasis on allegedly inflated and false WACs similar to the emphasis in the *Commonwealth of Massachusetts* case (¶ 8); (2) allegations concerning the "role of PBMs in the AWP Scheme" (¶¶ 11, 136, 137-145)⁸; and (3) citation to the investigation of the House Committee on Energy and Commerce into pharmaceutical reimbursements and rebates under Medicaid (¶¶ 154-57) and the Senate Finance Committee's investigation into some defendants' nominal pricing practices (¶159).⁹

On February 1, 2006, the Court granted Nassau County's motion for leave to file its Second Amended Complaint. Other than the Nassau SAC's retention of the RICO claim, and its allegations specific to Nassau, the pleading is not materially different from the Consolidated Complaint. Accordingly, defendants move to dismiss both Complaints for the same reasons.

⁸ These allegations are irrelevant because the PBMs have no role in New York's Medicaid program.

⁹ "Nominal" prices are defined by statute as "such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount". 42 U.S.C.A. § 1395w-3a(c)(2)(B). Transactions at such nominal prices are excluded from a manufacturer's best price reporting obligation under the Medicaid rebate statute. 42 U.S.C.A. § 1396r-8(c)(1)(C)(ii)(III). The Senate Finance Committee is investigating whether the definition and/or the exception to the rebate statute should be amended in some fashion.

Argument

POINT I

THE CLAIMS IN SUFFOLK DISMISSED UNDER RULE 12(b)(6) SHOULD ALSO BE DISMISSED IN THE CONSOLIDATED COMPLAINT AND THE NASSAU SAC**A. This Court's Decisions In *Suffolk* Are "Law of the Case" And/Or *Stare Decisis***

Counts I, III, V, and VII of the Consolidated Complaint and Counts I, II, V, VI, and VIII of the Nassau SAC should be dismissed under the "law of the case" doctrine and/or *stare decisis*. Law of the case doctrine posits that when a court decides a question of law in a case – as this Court did in dismissing under Rule 12(b)(6) the same Counts in *Suffolk* and *Massachusetts* – "that decision should continue to govern the same issues in subsequent stages." *Christianson v. Colt Indus.*, 486 U.S. 800, 816 (1988).¹⁰ The doctrine is "grounded in important considerations related to stability in the decision-making process, predictability of results, proper working relationships between trial and appellate courts, and judicial economy." *United States v. Rivera-Martinez*, 931 F. 2d 148, 151 (1st Cir. 1991). "Perpetual litigation of any issue – jurisdictional or nonjurisdictional – delays, and therefore threatens to deny, justice." *Christianson*, 486 U.S. at 816 n.5.

Law of the case doctrine applies to coordinated cases involving the same or similarly situated parties. *Watson & Son Pet Supplies v. IAMS Co.*, 107 F. Supp. 2d 883, 888 (S.D. Ohio 1999). Here, the New York "county" cases are coordinated not merely as a result of their being placed in a single multi-district litigation, but also because the parties formally stipulated that the Westchester, Rockland and New York City Complaints "contain[] similar allegations and claims against certain of the same defendants as the Amended Complaint filed by

¹⁰ "It is well settled in this circuit that dismissal for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) is a final decision on the merits." *United States ex rel. Karvelas v. Merlrose-Wakefield Hosp.*, 360 F.3d 220, 241 (1st Cir. 2004). In the absence of a clear statement to the contrary, such dismissal is presumed to be with prejudice. *Id.*

the County of Suffolk in MDL 1456” and that “judicial economy” dictates that the decisions on the pleadings in *Suffolk* guide defendants’ responsive pleadings in those actions. Formal concessions in a stipulation are judicial admissions binding upon the parties making them. *Keller v. United States*, 58 F.3d 1194, 1199 n.8 (7th Cir. 1995); *American Title Ins. Co. v. Lacelaw Corp.*, 861 F.2d 224, 226 (9th Cir. 1988).

Even if the county cases were not coordinated for law-of-the-case purposes, the above-referenced Counts of the Consolidated Complaint and the Nassau SAC should be dismissed under the principle of *stare decisis*, which “renders the ruling of *law* in a case binding in future cases before the same court or other courts owing obedience to the decision.” *Stewart v. Dutra Construction Co.*, 230 F.3d 461, 467 (1st Cir. 2000) (emphasis in original). The judiciary’s “precedent-based system of justice places a premium on finality, stability, and certainty of law, particularly in the field of statutory construction,” *id.*, which is the “field” this Court covered in *Suffolk and Massachusetts*.¹¹ Thus, the *Suffolk* decisions have *stare decisis* effect in the *New York City* case and the cases of all the counties other than Suffolk, regardless of whether those cases are coordinated with or managed separately from *Suffolk*.

¹¹ “[T]he essential principles of *stare decisis* are: (1) an issue of law must have been heard and decided; (2) if an issue is not argued, or though argued is ignored by the court, or is reserved, the decision does not constitute a precedent to be followed; (3) a decision is *stare decisis* despite the contention that the court was not properly instructed by counsel on the legislative history, or that the argument was otherwise insufficient; (4) a decision may properly be overruled if seriously out of keeping with contemporary views or passed by in the development of the law or proved to be unworkable; and (5) there is a heavy presumption that settled issues of law will not be reexamined. Another factor to be considered in determining whether to give an opinion *stare decisis* effect is whether the party was aware of the prior litigation but failed to intervene or file an amicus brief on appeal.” *State Police for Automatic Retirement Ass’n v. DiFava*, 164 F. Supp. 2d 141, 155 (D. Mass. 2001) (citations omitted).

B. There Is Nothing “New” in the Consolidated Complaint or the Nassau SAC that Would Support Reconsideration of this Court’s Rulings on RICO, the Rebate Statute, the Rebate Agreement, or the Elements of Fraud

The Court will find nothing in the Consolidated Complaint or the Nassau SAC that should lead it to revisit the merits of the allegations that it previously dismissed.

1. *RICO*

This Court has now *twice* dismissed under Fed. R. Civ. P. 12(b)(6) and 9(b) claims alleging a Manufacturer-Publisher RICO enterprise: first, in response to the motion to dismiss the class claim in the Amended Master Consolidated Complaint, *In re Pharm. Wholesale Price Litig.*, 307 F. Supp. 2d at 204 (*citing U.S. v. Turkette*, 452 U.S. 576, 590 (1981)) and, second, in response to the motion to dismiss Suffolk’s Amended Complaint. *Suffolk I*, 339 F. Supp. 2d. at 175. Nassau’s SAC offers no basis for revisiting those decisions. Indeed, the only relevant language in the Nassau SAC that was not in the Suffolk Amended Complaint is the following:

The AWP scheme is reliant on the cooperation and coordination of both the Publishers and the Manufacturers. The Manufacturers’ ability to market the spread created by the publication of false and inflated AWPs depends on the cooperation of the Publishers, through both misfeasance in converting WACs into AWPs, and nonfeasance in not independently affirming the accuracy of the AWPs as they had in the past. *The Publishers’ entire product was reliant on the information supplied to them by the Manufacturers*, and to protect that supply the Publishers forewent their duty to report honest AWP to the Medicare system and the public at large. Without both groups participating in the scheme, the AWP scheme could not have succeeded. (Nassau SAC at ¶ 693 (emphasis added)).

The highlighted allegation is similar to that which the Court found fatal to an enterprise allegation in *Suffolk* – specifically, that the defendants controlled the prices at issue and that the publishers were primarily conduits. *Suffolk I*, 339 F. Supp. 2d. at 175. Also, as in *Suffolk*, Nassau has failed entirely to provide “details about the interaction and the manufacturers sufficient to meet Federal Rule of Civil Procedure 9(b).” *Id.* Accordingly, the claim should again be dismissed.

2. *Implied Private Right Of Action Under The Best Price Statute*

This Court has held that federal statutes give rise to civil actions only where Congress has unambiguously provided for both a private right and a private remedy. *Suffolk I*, 339 F. Supp.2d at 176-77 (*citing Alexander v. Sandoval*, 532 U.S. 275, 286, 287 (2001) (citing cases)). The Court dismissed Suffolk's claim under the Medicaid rebate statute, 42 U.S.C. 1396r-8, because a reading of the statute "cement[ed] the conclusion that Congress did not intend to create an implied remedy . . ." *Id.* at 177. For the same reason, this Court dismissed a similar claim the Commonwealth of Massachusetts asserted under 42 U.S.C. 1396r-8. *See Commonwealth of Mass.*, 357 F. Supp. 2d at 325-27. Neither the Consolidated Complaint nor the Nassau SAC point to anything "new" in the statute that could plausibly alter the holdings in *Suffolk* and *Commonwealth of Mass.* Accordingly, the claims under 42 U.S.C. 1396r-8 should be dismissed.

3. *Third-Party Beneficiaries of the Rebate Agreements*

This Court dismissed Suffolk's claim for breach of the federal rebate agreement because it was unable to "show a clear indication *on the face of the contract* of an intent either to benefit Suffolk or to benefit a class that includes Suffolk." *Suffolk I*, 339 F. Supp. 2d. at 178 (emphasis added). In the Consolidated Complaint and the Nassau SAC, plaintiffs seek to cobble together allegations not in Suffolk's Amended Complaint that, they believe, support the requisite inference of intent to benefit Counties. In fact, each of these points was previously argued to the Court in the motion-to-dismiss briefing in *Suffolk* and, more importantly, each is extraneous to the agreement at issue.

For example, the pleadings now state that the federal government approved New York's Medicaid Plan -- which plan plaintiffs allege imposed rights and duties on local social

service districts -- at the time that the federal government entered into its rebate agreements with manufacturers. (Cons. Comp. ¶¶ 103, 115-120, 879-880; Nassau SAC ¶ 103). Since the Secretary of Health and Human Services signed the rebate agreements after having approved New York's overall Medicaid plan, plaintiffs reason, that was enough to confer third-party beneficiary status on plaintiffs.

Plaintiffs made these exact same arguments in the briefing relating to *Suffolk* (*see Suffolk Opp.*, at 1, 20, 24, 29-31; *Suffolk Sur-Reply*, at 1-2, 11) and the Court rejected them. The Court held that references to the "structure" and "legislative history" of the Medicaid rebate statute, the concept of "cooperative federalism" and the roles of the local social service districts within New York Medicaid are not a substitute for an analysis of the rebate agreements themselves. The language of the agreements controls. *Suffolk I*, 339 F. Supp. 2d. at 178. Because the Consolidated Complaint and the Nassau SAC contain no new allegations *concerning the rebate agreements themselves*, the contract claims should again be dismissed.

4. *Common Law Fraud*

The Court dismissed Suffolk's common law fraud claim because only New York State, not its counties, had the authority to set Medicaid reimbursement rates and therefore only New York State could possibly have relied on the allegedly fraudulent WACs or AWPs. *See County of Suffolk*, 339 F. Supp. 2d at 180-81. The Court cited *Cement & Concrete Workers Dist. Counsel Welfare Fund, Pension Fund, Legal Serv. Fund & Annuity Fund v. Lollo*, 148 F.3d 194, 196 (2d Cir. 1998) for the principle that a plaintiff cannot base a common law fraud claim on alleged reliance by a third-party. *Suffolk I*, 339 F. Supp. 2d. at 180-81. Neither the Consolidated Complaint nor the Nassau SAC contains, or properly could contain, any allegations that would warrant the Court's reconsideration of this issue.

5. *Social Services Law § 145-b (as to “Best Price” Claims)*

Plaintiffs again allege, without any particularity whatsoever (*see* Point IV *infra*), that defendants violated N.Y. Soc. Serv. Law § 145-b by routinely making lower Medicaid rebate payments to the State than they should have, because they had misrepresented the “best prices” on which those rebates were calculated. The Court dismissed precisely this claim by Suffolk, because that statute does not “encompass[] statements [made by defendants] to lower payments *made to* the State, as opposed to statements made to *receive payment from* the State.” *Suffolk I*, 339 F. Supp. 2d. at 180 (emphasis added). Neither the Consolidated Complaint nor the Nassau SAC make any new allegation that could remedy this fatal defect. Plaintiffs claim merely (a) that defendants made false statements regarding best price and (b) as a general proposition, New York’s Medicaid “overpays” when the State does not receive as much of a rebate as it should. (Cons. Comp. ¶ 119.) Clearly, claims based on allegedly insufficient payments made *to* the State cannot pass muster under the Court’s interpretation of Section 145-b as extending only to payments made *by* the State. This Court should again dismiss plaintiffs’ “best price” claims asserted under Section 145-b.

POINT II

THE GBL § 349 CLAIM AND THE ALLEGED IMPLIED PRIVATE RIGHTS OF ACTION UNDER NEW YORK STATE LAW SHOULD ALSO BE DISMISSED

A. General Business Law Section 349

This Court noted in its September 30, 2004 Order that, “in New York, the State reimburses providers directly for pharmaceuticals under its Medicaid system . . . and bills each county for twenty-five percent of the costs associated with the citizens of that county.” *Suffolk I*,

339 F. Supp. 2d. at 174 (citations omitted).¹² Suffolk's claimed damages as a result of defendants' alleged inflation of AWPs and WACs or alleged underpayments of Medicaid rebates are thus entirely derivative of the alleged damages attributed to New York State.

In its September 30, 2004 Order, this Court declined to make any general pronouncements on the lack of standing of indirect purchasers or derivative plaintiffs under New York law. *Suffolk I*, 339 F. Supp. 2d. at 176 ("state statutes may reject common law . . . and may ... allow[] suit on . . . derivative claims"). Instead, the Court reserved decision on the GBL § 349(a) claim in light of the anticipated decision by the New York Court of Appeals in *Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris, USA*. ("BCBSNJ") on this very issue. *Id.* The New York Court of Appeals has since rendered its decision and made it clear that the counties have no GBL § 349(a) claims.

On October 19, 2004, the New York Court of Appeals held that only direct purchasers have standing to sue under GBL § 349(a):

[P]laintiff argues that in enacting General Business Law § 349, the Legislature intended to abrogate the common-law rule and permit recovery for derivative injuries. But neither the text of the statute nor the legislative history reflect [such] an intent by the Legislature

* * *

[W]e will not presume an intent to include recovery for derivative injuries within the scope of the statute in the absence of a clear indication of such intent from the Legislature.

BCBSNJ, 3 N.Y.3d 200, 206-07, 785 N.Y.S.2d 399, 403 (2004). Under New York law, the Court of Appeals said, only the party "directly" and "non-derivatively" injured by the alleged deception has standing to sue. *Id.* at 208.

¹² These bills are a small part of a complex accounting system in which not only Medicaid dollars, but other financial obligations between the State and its counties are set-off against one another. *Id.* at 174 n. 3 (referring to defendants' motion papers).

It is New York State, not any of its counties, that sets New York's Medicaid payment formula for prescription drugs and for paying Medicaid providers. *See Suffolk I*, 339 F. Supp. 2d. at 108-81 (dismissing the common law fraud claim). Even if New York State were to rely on a deceptive AWP in doing so (which defendants dispute), any injury to a New York county would be entirely derivative of the State's injury by virtue of the county's statutory obligation to reimburse a portion of the State's Medicaid costs. Similarly, these plaintiffs, whom this Court has held are not third-party beneficiaries of defendants' Medicaid rebate agreements with the federal government (Suffolk Mem. at 12-14), have no standing to sue under GBL § 349 for alleged underpayment of Medicaid rebates.

B. Implied Rights of Action Under New York Health Statutes And Regulations

Plaintiffs assert implied rights of action under two New York Social Services Law statutes (one of which is a penal provision) and under administrative regulations. In its earlier opinion, the Court declined to address these causes of action. *Suffolk I*, 339 F. Supp. 2d. at 182-83. It should now dismiss them.

Generally, under New York law, a plaintiff must satisfy a three-prong test to demonstrate that a private right of action can be implied from a New York state statute: (1) plaintiff must be part of the class for whose particular benefit the statute was enacted; (2) recognition of a private right of action would promote the legislative purpose; and (3) creation of an implied private right of action would be consistent with the legislative scheme. *See Sheehy v. Big Flats Cnty. Day, Inc.*, 73 N.Y.2d 629, 632-33, 541 N.E.2d 18, 20, 543 N.Y.S.2d 18, 20 (1989); *Burns Jackson Miller Summit & Spitzer v. Lindner*, 59 N.Y.2d 314, 325, 451 N.E.2d 459, 463-66, 464 N.Y.S.2d 712, 716 (1983); *CPC Int'l Inc. v. McKesson Corp.*, 70 N.Y.2d 268, 276-

77, 514 N.E.2d 116, 118-19, 519 N.Y.S.2d 804, 807 (1987).¹³ “If one of these prerequisites is lacking, the claim will fail.” *Pelaez v. Seide*, 2 N.Y.3d 186, 200, 778 N.Y.S. 2d 111, 118 (2004), citing *O’Connor v. City of New York*, 58 N.Y.2d 184, 460 N.Y.S.2d 485 (1983).

All of plaintiffs’ implied causes of action fail because they are contrary to New York’s division of labor between federal and state enforcement authorities on the one hand and county officials on the other in combating Medicaid fraud. As the Executive Director of New York State Association of Counties, Stephen J. Acquario, Esq., has recently testified, the Counties’ role is limited to policing “recipient fraud” -- fraud by individuals *located in the counties* who improperly receive Medicaid benefits. NY Counties’ Executive Dir. Test. at 4 attached hereto as Exhibit A. As to “provider fraud” (in this case, fraud by the pharmacies as allegedly facilitated by the AWPs of the manufacturers), “the ability to enforce administrative and criminal actions . . . remains with state and federal officials.” *Id.* (emphasis added). Defendants now turn to the particular implied rights of action alleged.

1. *Section 367-a(7)(d)*

Social Services Law § 367-a(7)(d) states:

“Notwithstanding any inconsistent provision of law, if a manufacturer . . . has entered into a rebate agreement with the department or with the federal secretary of health and human services on behalf of the department under section 1927 of the federal social security act, the department shall reimburse for covered outpatient drugs which are dispensed under the medical assistance program to all persons . . . only pursuant to the terms of the rebate agreement between the department and such manufacturer . . . The department in providing utilization data to a manufacturer (as provided for under section 1927(4)(b)(1)(A) of the federal social security act) shall provide such data by zip code, if requested, for drugs covered under a rebate agreement.”

¹³ Federal courts apply the state-law decisional test when considering whether a right of action is implied in a state statute. See *Grenier v. Kennebec County*, 748 F. Supp. 908, 913 (D. Me. 1990) (applying Maine law to conclude that Maine statute did not provide implied private right of action).

As that language makes clear, this section does not aim to confer a particular benefit or protection on anyone, let alone local social service districts, as the first prong of *Sheehy* requires. Instead, it merely declares that the State will do what is necessary to comply with section 1927 of the federal Social Security Act, 42 U.S.C. § 1396r-8. The only duties imposed by this statute are on the State.

The statutory language further demonstrates that plaintiffs' theory of an implied private remedy also fails the second and third prongs of the *Sheehy* test. The statute contemplates that the New York State Department of Social Services, not the local social service districts, will direct enforcement and compliance efforts on behalf of New York's medical assistance program.¹⁴ At a minimum, it would be inefficient to allow individual counties to sue over Medicaid rebates that are calculated and paid on a state-wide level. Even worse, it could subject a single state-wide rebate calculation to inconsistent judgments in different counties. To quote again from the testimony of the New York Association of Counties' Executive Director:

The local role in Medicaid fraud and abuse control has been understandably limited by the State Health Department, as they [sic] must be assured that there is no duplication of effort, that proper audit procedures are followed, and that there is a consistent application of program requirements pursuant to federal and state regulations. (NY Counties' Executive. Dir. Test. at 6.)

Finally, just as this Court found under the federal rebate statute that Congress's express grant of enforcement powers to the Secretary of Health and Human Services negated the implication of such powers in other actors, the New York legislature's explicit grant of

¹⁴ For example, § 367-a(10)(d) states “[t]he *department* may bring and maintain an action against the provider ... for any claimed overpayments” (emphasis added). And § 367-a(10)(h) states “[t]he *department* may make the submission of the financial security required by this subdivision a condition of participation in the medical assistance program.” (emphasis added). On the other hand, when the legislature wanted to give the local social service district a right, it expressly did so. *See e.g.*, Section 367-a(2)(b) (“local social service district or the department shall be subrogated . . . to any rights [a recipient of Medicaid] may have to medical support or third-party reimbursement”). This contrast in statutory text is strong evidence that the New York legislature did not intend to give the counties any role on the subsection of Section 367-a that deals with federal Medicaid rebates.

enforcement powers to the “department” in Section 367-a “cement[s] the conclusion” (*Suffolk I*, 339 F. Supp. 2d. at 177), that the New York legislature did *not* intend to grant any enforcement powers to the counties by creating implied private remedies under the statute. *Hammer v. Amer. Kennel Club*, 1 N.Y.3d 294, 299 771 N.Y.S.2d 493, 495 (2003) (holding that no implied right of action existed because statute already provided for enforcement mechanisms and implication of private cause of action for another actor was incompatible with statutory scheme).

2. *New York Soc. Serv. Law § 366-b*

In the Count entitled “Fraud”, the Consolidated Complaint and the Nassau SAC purport to proceed under both the common law and an implied private right of action under New York Soc. Serv. Law § 366-b. Section 366-b is a catch-all penal statute which provides that, to the extent certain acts to defraud the Medicaid system are not already covered by the criminal code, they are made Class A misdemeanors under this Section. As shown above, New York counties have no authority to enforce penal provisions relating to Medicaid. *See e.g.* NY Counties’ Executive Dir. Test. at 4. It is inimical to the legislative intent to imply a private right of action in favor of the counties from a criminal statute. *Watson v. City of New York*, 92 F.3d 31 (2d Cir. 1996) (“Federal Courts are hesitant to imply private rights of action from state criminal statutes” without direct guidance from state courts) (*quoting In re Integrated Resources, Inc. Real Estate Ltd. Partnerships Sec. Litig.* 851 F. Supp. 556, 564 (S.D.N.Y. 1994); *Swartz v. FS&O Inc.*, 1991 WL 208056 (S.D.N.Y. 1991) (“Rarely is there a private right of action under a criminal statute”) (*Citing Chrysler Corp. v. Brown*, 441 U.S. 281, 99 S.Ct. 1705 (1979)); *Sardanis v. Sumitomo Corp.*, 279 A.D. 225, 718 N.Y.S.2d 66 (1st Dep’t 2001) (no private right of action for violation of state commercial bribery statute)).

3. *N.Y.C.R.R. § 515.2(b)(4) and (5)*

The New York Department of Social Services has promulgated various regulations to administer New York's Medicaid program. 18 N.Y.C.R.R. 500, *et seq.* These regulations are aimed at providers of health services, not manufacturers of pharmaceuticals. Furthermore, they explicitly contemplate enforcement by the Department through the administrative process, not by the counties through the courts.

Part 515 is entitled “*Provider Sanctions*”. (emphasis added.) The subsections that plaintiffs rely upon, § 515.2(b)(4) and (5), state that it is an “unacceptable practice” to “convert a medical assistance payment . . . to a use or benefit other than [one] intended by the . . . program” or to offer a “bribe or kickback” for, among other things, purchasing medical supplies for which payment is claimed under the program. These regulations are clearly aimed at medical providers.

The regulations also make clear that the “Authority to Sanction” for an “unacceptable practice” is lodged in “the department”, not the counties, in the exercise of the Department’s administrative “discretion” pursuant to certain “guidelines.” *See Sections 515.3 and 515.4.* The “sanctions” listed are “exclusion” from, “censure” or “conditional or limited participation” in the Medicaid program. Thereafter, “the department may *also* require the repayment of overpayments determined to have been made as a result of the unacceptable practice.” Section 515.3(b) (emphasis added). Thus, there is no authority to seek only monetary damages. Most importantly, the counties have been deliberately excluded from the administrative scheme. *See Testimony of Stephen J. Acquario at 5 (“counties do not have authority for administrative recovery overpayments . . . or the use of provider sanctions”).*

The regulations require notification provisions of proposed sanctions and restitution, and provide for an administrative hearing and appeals. Section 515.6; *see also* Part

519 (“Provider Hearings”). Only if the Department determines that a judicial “action or proceeding would be more efficient or effective or in the best interest of a program” does the Department reserve to itself “the right to initiate or participate in civil proceedings.” *See* Section 518.5(c).

Applying the Court of Appeals test under *Sheehy*, it is clear that implying a private right of action in favor of the counties to proceed in court for money damages would be entirely antithetical to the statutory scheme. Accordingly, this Court should dismiss the causes of action in the Consolidated Complaint and the Nassau SAC under N.Y.C.R.R. § 515.2(b)(4) and (5).

POINT III

THE N.Y. SOCIAL SERVICES LAW § 145-b CLAIM SHOULD ALSO BE DISMISSED AS TO PLAINTIFFS’ “AWP FRAUD” CLAIMS

Section 145-b(1)(a) of the New York Social Services law provides:

“It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to [the Medicaid program].”

Defendants recognize that the Court previously declined to dismiss the count in Suffolk’s complaint involving this statute on the theory that defendants’ conduct is encompassed by the phrase “on behalf of others”. *County of Suffolk*, 339 F. Supp. 2d. at 180. We restate our arguments here to preserve defendants’ right to appeal that ruling as against the newly-added plaintiffs in the Consolidated Complaint and the Nassau SAC and because we believe the Court’s prior ruling was erroneous.

Although the statute is not a model of clarity, what is clearly prohibited is the “obtain[ing]” of “payment from public funds for services or supplies furnished” to the Medicaid

program “by means of a false statement”. The language “on behalf of himself or others” does not alter the requirement that, to violate the statute, a defendant must have obtained public funds directly himself or as an agent of others. Since drug manufacturers do not obtain payment from the Medicaid program for drugs, they cannot be liable under the statute. Pharmacists and medical providers, not pharmaceutical manufacturers, are the parties that Medicaid reimburses for drugs.

The only New York court to interpret the statute in this context agrees with this reading. *New York v. Pharmacia Corp., et al.*, Index Nos. 905-04, 905-03, 1150-03 slip op. (N. Y. Sup. Ct. June 1, 2004) involved allegations that were virtually identical to those made here. New York State sued a pharmaceutical manufacturer for allegedly publishing fraudulent AWPs. Relying on the plain language of the statute, the court found that § 145 applies to only those persons who *actually receive* payments from State funds. *Id.* at 10.

In its previous ruling, the Court distinguished *Pharmacia* on the ground that it did not address whether a fraudulent statement made on behalf of others to assist them in obtaining funds was a violation under Social Services Law § 145-b. The court in *Pharmacia*, however, necessarily addressed this issue because the allegation in that case was virtually identical to the allegation here. Although *Pharmacia* was decided by a trial court, the decision is sound, and there is no reason why this Court should not follow a New York court’s interpretation of New York law.¹⁵

¹⁵ This Court also noted that the *Pharmacia* court did not address the effect of subsection 1(c), which provides: For purposes of this section, a person, firm or corporation has attempted to obtain or has obtained public funds when any portion of the funds from which payment was attempted or obtained are public funds, or any public funds are used to reimburse or make prospective payment to any entity from which payment was attempted or obtained.

This section does not change the analysis. It simply defines what constitutes “obtain[ing of] public funds.”

Even if this Court finds that the language of the statute is ambiguous, the legislative history demonstrates that the statute was directed at “Medicaid providers who defraud the State . . .” (*Governor’s Bill Jacket 1975 Chapter 659, Budget Report ¶ 2.a.*)¹⁶ According to the Governor’s Memorandum: “Subdivision 1 makes unlawful any false statements or the concealment of any material fact *in an attempt to obtain or in the actual obtaining of payment for services from Medicaid funds.*” (*Id.; emphasis added.*) Numerous other statements in the Governor’s Bill Jacket are to the same effect. (*See, e.g., Memorandum Accompanying Comments on Bills Before the Governor for Executive Action* (“This bill would authorize the imposition of treble damages against any person, firm or corporation who fraudulently obtains or attempts to obtain public funds . . .”); *Department of Health* (“This bill . . . authorizes local social services districts . . . to bring civil actions for treble damages against any provider or supplier of services or supplies . . .”); *Association of Protestant Welfare Agencies* (“It is those who are directly responsible for the expense and receipt of money, the care of patients, and the maintenance of the facility who should be held accountable” under § 145-b.); *New York City* (“This bill would extend stringent penalties to providers of services . . .”.) (*July 24, 1975 letter from Berkeley D. Johnson, Jr., Chairman, Committee on Public Policy* (emphasis added)). There is nothing in the language of the bill or the legislative history which suggests that the bill was intended to reach alleged aiders and abettors, as opposed to persons who obtain funds directly or obtain funds on behalf of others by means of false statements. In sum, defendants cannot be held liable under § 145-b because they did not provide any medical services or supplies directly to Medicaid

¹⁶ In New York, the legislative history of bills is collected in the Governor’s Bill Jacket. The bill jacket contains comments of proponents and supporters on the need for and purpose of the bill. A copy of the bill jacket for this section was submitted to the Court after oral argument on the original motion to dismiss the *Suffolk County* complaint and is annexed hereto as Exhibit B.

recipients, and they did not obtain (or attempt to obtain) public funds for on behalf of providers of such services or supplies. *See Pharmacia* at 10.

POINT IV

THE UNJUST ENRICHMENT CLAIM AND ALL OTHER CLAIMS NOT OTHERWISE DISMISSED UNDER RULE 12(b) SHOULD BE DISMISSED UNDER RULES 8(a) AND 9(b)

A. Application of Rule 9(b) to Unjust Enrichment¹⁷ and Other Claims

Claims including unjust enrichment premised in whole or in part on fraud must be alleged with the specificity required by Rule 9(b). *See Daly v. Castro Llanes*, 30 F. Supp. 2d 407 (S.D.N.Y 1998) (unjust enrichment claim “premised on fraud” is subject to Rule 9(b)); *Ramapo Land Co., Inc. v. Consolidated Rail Corp.*, 918 F. Supp. 2d 123, 128 (S.D.N.Y. 1996) (Unjust enrichment claim subject to Rule 9(b) when based entirely on claim of misrepresentation). Here, plaintiffs claim that defendants have been unjustly enriched because of defendants’ “unlawful conduct”, or fraudulent price manipulation. Because the “unlawful” or fraudulent conduct is the only basis for plaintiffs’ unjust enrichment claim, plaintiffs cannot escape the specificity requirements of Rule 9(b).

¹⁷ Plaintiffs’ claim for unjust enrichment must also be dismissed for lack of standing. An unjust enrichment claim “requires some type of direct dealing or actual, substantive relationship with a defendant.” *Redtail Leasing, Inc. v. Bellezza*, 1997 WL 603496, *8 (S.D.N.Y. 1998) (applying New York law). An unjust enrichment claim is an equitable alternative to a contractual claim in law, and, therefore, requires a relationship between the parties approaching a contractual relationship. *Reading International, Inc. v. Oaktree Capital Management LLC*, 317 F.Supp.2d 301 (S.D.N.Y. 2003) (applying New York law). Here, the Counties have failed to allege that they had *any* relationship with the defendant manufacturers, much less a relationship approaching a contractual one. Indeed, with respect to the counties’ best price claims, this Court ruled that New York counties are not third party beneficiaries of rebate agreements between the Secretary of Health and Human Services and the defendant manufacturers. *Suffolk I*, 339 F. Supp. 2d at 177-79. Nor have plaintiffs alleged any other fact or circumstance illustrating any thing close to a relationship of any kind with the defendants sufficient to support their claim for unjust enrichment.

Furthermore, any attempt to assert unjust enrichment claims based on Best Price reporting is barred as a matter of New York law by the Rebate Agreements. *See MacDraw, Inc. v. CIT Group Equip. Fin.*, 157 F.3d 956, 964 (2d Cir. 1998) (citations omitted); *Granite Partners, LP v. Bear, Stearns & Co.*, 17 F. Supp. 2d, 275, 311 (S.D.N.Y. 1998) (citations omitted). Plaintiffs’ apparent attempt to avoid this established law by alleging these claims “to the extent the court determines there is no contractual relationship between Counties and the defendants.” (Cons. Comp. ¶ 903), cannot save this claim. Such alternative pleading would be permissible only if there were “a bona fide dispute as to the existence of” the Rebate Agreement. E.g., *Waxman v. Vipco Pick Up & Processing Servs.*, 2003 U.S. Dist. LEXIS 19295 (S.D.N.Y. 2003).

B. The Best Price Claims

The Court dismissed Suffolk's Best Price claims as against drugs "for which [the County] has not alleged particular facts" (November 23, 2004 *Clarification Order* at 1) on the ground that "[for] most companies, Suffolk has not tied the Best Prices claims to any particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices." *Suffolk II*, 2004 WL 2387125 at *2. The Court noted that Suffolk's pleading did not allege "(1) the allegedly fraudulent or false price reported to the state for any specific drug or (2) any information showing a company-wide scheme to misstate best prices." *Suffolk II*, 2004 WL 2387125 at *3. The combined effect of these orders was to dismiss all or virtually all of the Best Price claims for lack of specificity -- even those that did not have a fraud element.

The new Complaints should fare no better. The main differences¹⁸ between the allegations in the Consolidated Complaint and the Nassau SAC that relate to "best price" and those in the Suffolk Amended Complaint are citations to two investigations by Congressional committees: one by the House Committee on Energy and Commerce (*e.g.*, Cons. Comp. ¶ 156) and the other by the Senate Finance Committee (*e.g.* Cons. Comp. ¶ 159).¹⁹ But mere mention of

¹⁸ With respect to the GSK defendants, the Consolidated Complaint and the Nassau SAC add that the "deep discounts" allegedly offered for GSK drug Zantac were not "accounted for in GSK's calculation of Best Price." (Cons. Comp. at ¶ 520; Nassau SAC at ¶ 436.) Similarly, with respect to Biogen Idec Inc., the complaints add that alleged free samples and "defacto discounts" were "not properly accounted for" in the best price calculations for Biogen drugs. (Cons. Comp. at ¶¶ 331-336; Nassau SAC at ¶¶ 312-316). With respect to Wyeth, the Consolidated Complaint and the Nassau SAC add that the "deep discounts" allegedly offered for Wyeth's drug Protonix were not "accounted for in Wyeth's calculation of Best Price." (Cons. Comp. at ¶ 821; Nassau SAC at ¶ 712.) Plaintiffs have also added in both Complaints some new allegations concerning Merck & Co., Inc. which are addressed in its separate memorandum. These additional sweeping phrases fail to add the specificity this Court has continually required of the plaintiffs' pleadings.

¹⁹ Even if Suffolk did not make reference to these investigations in its amended complaint, it did rely on them in its losing response to the motion by the "Suffolk 13" and others to dismiss the claims against them. *See Affidavit*

the existence of these investigations does not satisfy the pleading requirements set down by this Court for Best Price claims. Both the Consolidated Complaint and the Nassau SAC are virtually devoid of any specific instance of defendants misreporting “best price”.²⁰ Instead, the pleadings, like Suffolk’s Amended Complaint, merely allege in an undifferentiated fashion that potentially every “best price” calculation for every drug in the United States purchased by the counties for over a decade was wrong. Thus, any remaining “best price” claims not dismissed under Fed. R. Civ. P. 12(b)(6) should be dismissed under Rules 9(b) and 8(a).

C. The AWP Fraud/WAC Fraud Claims

1. *Physician-Administered Drugs*

As this Court noted in its first *Suffolk* decision, “[u]nder the New York Medicaid statute, physician-administered drugs are billed by the physician at the ‘actual cost of the drugs to practitioners.’” *Suffolk I*, 339 F. Supp. 2d. at 174 (citing N.Y. Soc. Serv. L. § 367-a(9)(a)). The Consolidated Complaint impliedly recognizes this, noting that “New York State law has provided that Medicaid will pay providers for defendants’ drugs that are ‘self-administered,’ i.e., dispensed at a pharmacy, based on AWPs for such drugs.” Cons. Comp. at ¶ 83 (citing N.Y. Soc. Serv. L. § 367-a(9)). Nowhere in the Consolidated Complaint or in the Nassau SAC do the plaintiffs attempt to particularize how their theory of AWP fraud or WAC fraud is applicable to physician-administered drugs in the face of a statutory mandate that payments for such drugs be made at

of Aaron Hovan, Esq., sworn to on November 16, 2004, at ¶ 2 and Exhibit A (citing the investigations among others). Thus, the allegations have been previously considered by this Court.

²⁰ See e.g., FN 18, *supra*.

“actual cost.”²¹ Accordingly, the pleadings fail to satisfy Fed. R. Civ. P. 8(a) and 9(b) as to physician-administered drugs.

2. *WAC Allegations*

Just as plaintiffs’ conclusory allegations as to AWP are insufficient under Rule 9(b), the allegations as to Wholesale Acquisition Cost (“WAC”) are equally defective. In the *Massachusetts* case, plaintiff accused defendants of “causing it to overpay pharmacies and other providers for *generic* prescription drugs under the Commonwealth’s Medicaid Program by fraudulently inflating the “Wholesale Acquisition Cost” (“WAC”) of covered drugs.” 357 F. Supp. 2d at 317 (emphasis added). Now, New York City, the Counties in the Consolidated Complaint, and Nassau in its SAC make the same claim about the WAC of every drug – brand-name and generic. Plaintiffs fail, however, to provide any specific allegation regarding particular drugs and the amount of any alleged inflation. Neither complaint alleges any facts to show that the WAC of any particular drug of any particular defendant was untrue, let alone fraudulent. As the Court concluded in its subsequent Memorandum and Order in *Commonwealth of Massachusetts* (dated April 5, 2005), generalized allegations as to all defendants are not enough: the complaint must identify each individual drug and provide factual allegations about why the WAC on that specific drug was fraudulent. *Memorandum and Order* at 1.

²¹ Many of the allegations of “spreads” between AWP and provider acquisition cost in the Consolidated Complaint and the Nassau SAC relate to physician-administered drugs, such as BMS drugs Cytoxin, Vepesid, Blenoxane and Amikin (Cons. Comp. ¶¶ 379-384; Nassau SAC ¶¶ 355-359); Bayer drugs Gammimune-N, Kogenate and Immune Globulin (Cons. Comp. ¶¶ 316-317; Nassau SAC ¶¶ 298-299,30); Amgen drugs Neupogen, Aranesp, Epothen, and Neulasta (Cons. Comp. ¶¶ 235, 228-233 and Ex. A; Nassau SAC ¶ 233); GSK drugs Zofran and Kytril (Nassau SAC at Ex. A.); Immunex drugs leucovorin calcium and methotrexate sodium (Cons. Comp. ¶¶ 237-238; Nassau SAC ¶ 234); Pharmacia drugs Vincasar, Etoposide, Cyclophosphamide, Testosterone Cypionate, Heparin Lock Flush, Cytarabine, Amphotericin B, Fluorouracil, Methylprednisolone Sodium Succinate, Bleomycin Sulfate, Toposar and Adriamycin RDF (Cons. Comp. ¶¶ 670-676; Nassau SAC ¶¶ 570-574); Sanofi/Aventis and Abbott drugs Anzemet Injectable, Factor VIII/Biocluate, Factor VIII/Helixate, and Gammar (Cons. Comp. ¶¶ 694, 701-702; Nassau SAC ¶ 203); Schering drug Intron A (Cons. Comp. ¶ 712); and Abbott drug Vancomycin Hydrochloride (Nassau SAC ¶ 207). The Complaints assume that these spreads apply even though New York’s Medicaid payment regime for these drugs is based on the physician’s cost and not on AWP or WAC.

3. “*Market Price*”

Paragraph 20 of the Consolidated Complaint refers to Exhibit B, which is described as a chart of “the reported AWPs for certain of defendants’ drugs and the available wholesale prices for these same drugs.” *See Cons. Comp.* at Ex. B. Exhibit B itself contains for the selected drugs the following headings: “Price Date”, “Fraudulent AWP”, “Market Price” and percentage “Spread” between the AWP and Market Price.²² The Nassau SAC contains a similar chart. Both of the charts and their allegations of spreads are highly misleading; neither satisfies Rule 9(b).

First, the comparison between AWP and Market Price appears to be irrelevant because paragraphs 7-8 of the Consolidated Complaint and paragraph 6 of the Nassau SAC each effectively state that “[t]his case is not about the 20-25% mark up between WAC and AWP. This case concerns that . . . WAC itself is false” (*Cons. Comp.* ¶¶ 7-8.) If the spread mark-up between WAC and AWP is out of the case, then it makes no sense to compare AWP to market price. At a minimum, plaintiff should be comparing WAC to market price.

Second, the time period selected in the Exhibit is limited to 2000, even though the Complaint asserts claims for the period 1992 to date. Neither the Consolidated Complaint nor the Nassau SAC indicate which drugs were on patent at the time periods on Exhibit B, or which were subject to therapeutic or generic competition at that time. The point is that one cannot adequately particularize a complaint that purports to sue on thousands of drug transactions from 1992 to the present simply by including a chart that presents selected drug prices in 2000.

Finally, as to drugs that were subject to FULs (*i.e.* those that were subject to generic competition and for which “federal upper limits” of Medicaid reimbursement had been

²² Plaintiffs have never adequately explained their source(s) for the so-called “Market Prices”. They contend that they are from an entity called “McKesson/Servall”, but defendants do not know of such an entity, nor can defendants relate the prices that plaintiffs list to prices in defendants’ own databases.

set), the comparison between AWP or WAC and the alleged market price is irrelevant. The FULs are much lower than the AWPs cited and thus the alleged “spreads” did not exist in practice. For example, for the BMS drug Capozide in 25 mg. tablet form, Exhibit B alleges an AWP of \$106.90 and a market price of \$16.69 for a spread of 540.66%. Exhibit C to the Consolidated Complaint, however, recognizes that there was a FUL for that same product of \$23.59. Thus, the “spread” between that FUL and the market price was only 41.3%, which does not support an inference of fraud.

In sum, the AWP (or WAC) fraud allegations relating to physician-administered drugs do not make sense in the context of New York’s use of provider acquisition cost. The allegations concerning pharmacy-dispensed drugs fail under Fed. R. Civ. P. 8(a) and 9(b) for the same reasons that the Court articulated in its October 26, 2004 and April 8, 2005 Orders: there are no factual allegations from which an inference of fraud can reasonably be made.

Conclusion

For the foregoing reasons, the Court should dismiss in their entirety (1) the Consolidated Complaint (of New York City and all plaintiff New York Counties other than Nassau) and (2) the Second Amended Complaint of Nassau County.

Dated: March 3, 2006

Respectfully submitted,

ON BEHALF OF ALL DEFENDANTS SERVED
IN ACCORDANCE WITH F.R.C.P. 4 OR WHO
HAVE WAIVED SERVICE

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CERTIFICATE OF SERVICE

I, Lyndon M. Tretter, hereby certify that on March 3, 2006, I have caused a true and correct copy of the foregoing motion on all counsel of record by electronic service, pursuant to Paragraph 11 of the Case Management Order No. 2, by sending a copy of Lexis/Nexis for posting and notification to all parties.

/s/ Lyndon M. Tretter

Lyndon M. Tretter